HOUSE OF REPRESENTATIVES

KENTICKT CENERAL ASSEMBLY AMENDMENT FORM OF THE CONTROL OF THE CON

Amend printed copy of HB 502/HCS 1

On page 1, delete lines 10 to 22 and insert the following:

- "(c) 1. "Direct-to-consumer genetic testing company" means an entity that:
 - a. Offers genetic testing products or services directly to a consumer; or
 - b. Collects, uses, or analyzes genetic data that resulted from a direct-toconsumer genetic testing product or service and was provided to the company by a consumer.
 - 2. "Direct-to-consumer genetic testing company" does not include any entity only when they are engaged in collecting, using, or analyzing genetic data or biological samples in the context of research, as defined in 45 C.F.R sec. 164.501, conducted in accordance with the Federal Policy for the Protection of Human Subjects, 45 C.F.R. pt. 46, the Good Clinical Practice Guideline issued by the International Council for Harmonisation, or the United States Food and Drug Administration Policy for the Protection of Human Subjects under 21 C.F.R. pts. 50 and 56;"

Amendment No. HFA	Rep. Danny Bentley
Committee Amendment	Signed:
Floor Amendment $\left(\begin{array}{c} 1 \\ 1 \end{array} \right) \left(\begin{array}{c} 1 \\ 1 \end{array} \right) \left(\begin{array}{c} 1 \\ 1 \end{array} \right) \left(\begin{array}{c} 1 \\ 1 \end{array} \right)$	IRC Drafter:
Adopted:	Date:
Rejected:	Doc. ID: XXXX